



GAU2814

Patent
Attorney's Docket No. 032005-120

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#a IDS
11-23-01
R Stokes

In re Patent Application of

Mark ASHBY, et al.

Group Art Unit: 2814

Application No.: 09/960,389

Examiner: unassigned

Filed: September 24, 2001

For: DEVICE AND METHOD FOR
FACILITATING MEMOSTASIS OF A
BIOPSY TRACT

RECEIVED
NOV 20 2001
TECHNOLOGY CENTER 2000

**INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- ☒ [X] No additional fee for submission of an IDS is required.
- ☐ [] The fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ [] A certification under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ [] A certification under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ [] Charge \$_____ to Deposit Account No. 02-4800 for the fee due.
- ☐ [] A check in the amount of \$_____ is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

By

Adam J. Cermak
Registration No. 40,391

Date: November 15, 2001



Patent
Attorney's Docket No. 032005-120

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
)
Mark ASHBY, et al.) Group Art Unit: 2814
)
Application No.: 09/960,389) Examiner: unassigned
)
Filed: September 24, 2001)
)
For: DEVICE AND METHOD FOR)
FACILITATING HEMOSTASIS OF A)
BIOPSY TRACT)

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited was submitted in Application No. 09/382,160 upon which is based a claim for priority under 35 U.S.C. § 120.

U.S. Patent No. 1,578,517
U.S. Patent No. 2,086,580
U.S. Patent No. 2,761,446
U.S. Patent No. 2,814,294
U.S. Patent No. 4,000,741
U.S. Patent No. 4,323,072
U.S. Patent No. 4,340,066
U.S. Patent No. 4,390,018
U.S. Patent No. 4,645,488
U.S. Patent No. 4,744,364
U.S. Patent No. 4,790,819
U.S. Patent No. 4,852,568
U.S. Patent No. 4,890,612

RECEIVED
NOV 20 2001
TECHNOLOGY CENTER 2000

U.S. Patent No. 4,900,303
U.S. Patent No. 4,936,835
U.S. Patent No. 4,950,234
U.S. Patent No. 5,021,059
U.S. Patent No. 5,053,046
U.S. Patent No. 5,061,274
U.S. Patent No. 5,080,655
U.S. Patent No. 5,108,421
U.S. Patent No. 5,163,904
U.S. Patent No. 5,167,624
U.S. Patent No. 5,192,300
U.S. Patent No. 5,192,301
U.S. Patent No. 5,195,988
U.S. Patent No. 5,220,926
U.S. Patent No. 5,221,259
U.S. Patent No. 5,275,616
U.S. Patent No. 5,325,857
U.S. Patent No. 5,334,216
U.S. Patent No. 5,383,899
U.S. Patent No. 5,388,588
U.S. Patent No. 5,391,183
U.S. Patent No. 5,419,765
U.S. Patent No. 5,467,780
U.S. Patent No. 5,478,352
U.S. Patent No. 5,479,936
U.S. Patent No. 5,486,195
U.S. Patent No. 5,522,850
U.S. Patent No. 5,540,715
U.S. Patent No. 5,591,205
U.S. Patent No. 5,601,602

U.S. Patent No. 5,649,547
U.S. Patent No. 5,681,279
U.S. Patent No. 5,716,375
U.S. Patent No. 5,725,498
U.S. Patent No. 5,769,086
U.S. Patent No. 5,775,333
U.S. Patent No. 5,902,310
U.S. Patent No. 581,235
U.S. Patent No. 2,465,357
U.S. Patent No. 2,492,458
U.S. Patent No. 2,507,244
U.S. Patent No. 2,558,395
U.S. Patent No. 2,597,011
U.S. Patent No. 2,824,092
U.S. Patent No. 2,899,362
U.S. Patent No. 3,157,524
U.S. Patent No. 4,515,637
U.S. Patent No. 4,587,969
U.S. Patent No. 4,588,395
U.S. Patent No. 4,619,261
U.S. Patent No. 4,619,913
U.S. Patent No. 4,829,994
U.S. Patent No. 4,850,960
U.S. Patent No. 4,929,246
U.S. Patent No. 5,007,895
U.S. Patent No. 5,310,407
U.S. Patent No. 5,336,480
U.S. Patent No. 5,383,896
U.S. Patent No. 5,431,639
U.S. Patent No. 5,437,631

U.S. Patent No. 5,526,822
U.S. Patent No. 5,529,577
U.S. Patent No. 5,545,178
U.S. Patent No. 5,558,853
U.S. Patent No. 5,591,204
U.S. Patent No. 5,645,566
U.S. Patent No. 5,653,730
U.S. Patent No. 5,665,107
U.S. Patent No. 5,741,223
U.S. Patent No. 5,810,806
U.S. Patent No. 5,830,130
U.S. Patent No. 4,619,913
U.S. Patent No. 5,370,656
U.S. Patent No. 5,775,333
U.S. Patent No. 5,800,389
U.S. Patent No. 6,161,034
U.S. Patent No. 4,708,718
U.S. Patent No. 5,242,683
U.S. Patent No. 5,322,515
U.S. Patent No. 5,385,550
U.S. Patent No. 5,858,008
U.S. Patent No. 6,027,471
U.S. Patent No. 6,027,482
U.S. Patent No. 6,071,301
U.S. Patent No. 6,086,607
U.S. Patent No. 6,183,497

European Patent No. 0 032 826 A2

United Kingdom Patent No. 1 569 660

French Patent No. 2 641 692

European Patent No. 0 476 178 A1
European Patent No. 0 482 350 A2
PCT Publication No. 96/08208
PCT Publication No. 98/06346
United Kingdom Patent No. 1 509 023
PCT Publication No. 99/66834
Russian Patent No. 782814
Russian Patent No. 1088709A

Vinant Chuang, M.D., et al., "Sheath Needle for Liver Biopsy in High-Risk patients," *Technical Developments and Instrumentation*, Radiology, Vol. 166, (1988): pg. 261 - 262.

Tony P. Smith, et al., "*Percutaneous Transhepatic Liver Biopsy with Tract Embolization*," Radiology, Vol. 198 (1996): pgs. 769 - 774.

S.A. Riley, et al., : "*Percutaneous Liver Biopsy With Plugging of Needle Tract: A Safe Method For Use In Patients With Impaired Coagulation*," The Lancet (August 1964)

Sigmund Silber, M.D., "*Rapid Hemostasis of Arterial Puncture Sites with Collagen in Patients Undergoing Diagnostic and Interventional Cardiac Catheterization*," Clinical Cardiology, Vol. 20, (December 1997): pgs. 981 - 992.

Marc Zins, M.D., et al. "*US-guided Percutaneous Liver Biopsy with Plugging of the Needle Track: A Prospective Study in 72 High-Risk Patients*," Radiology, Vol. 184 (1992) : pgs. 841-843.

David J. Allison, M.D., et al. "*Percutaneous Liver Biopsy and Tract Embolization with Steel Coils*," Radiology, Vol. 169 (1988) pgs. 261 - 263.

Ferdinand Kiemeneij, M.D., et al., "*Improved Anticoagulation Management After Palmaz Schatz Coronary Stent Implantation by Sealing the Arterial Puncture Site With a Vascular Hemostasis Device*," Catheterization and Cardiovascular Diagnosis, Vol. 30 (1993): pgs. 317 - 322.

J.P.M. Foran, et al., "*Early Mobilization After Percutaneous Cardiac Catheterisation Using Collagen Plug (VasoSeal) Haemostasis*," Br. Heart, Vol. 69 (1993) pgs. 424 - 429.

R. Schrader, et al., "*Collagen Application for Sealing of Arterial Puncture Sites in Comparison to Pressure Dressing: A Randomized Trial*", Catheterization and Cardiovascular Diagnosis (1992): pgs. 298-302.

J.S.R. Gibbs, et al., "*Femoral Arterial Hemostasis Using a Collagen Plug After Coronary Artery Stent Implantation*," Journal of Interventional Cardiology, Vol. 5, No. 2 (1992): 85 - 88.

William G. Kussmaul III, M.D., et al., "*Rapid Arterial Hemostasis and Decreased Access Site Complications After Cardiac Catheterization and Angioplasty: Results of a Randomized Trial of a Novel Hemostatic Device*," Journal of the American College of Cardiology, Vol. 25, No. 7 (1995): pgs. 1685 - 1692.

Timothy A. Sanborn, M.D., et al. "*Multicenter Randomized Trial Comparing a Percutaneous Collagen Hemostasis Device With Conventional Manual Compression After Diagnostic Angiography and Angioplasty*," Journal of the American College of Cardiology, Vol. 25, No. 7 (1993): pgs. 1273 - 1279.

Pharmacia & Upjohn Manufacturer Brochure "*Gelfoam Sterile Sponge, Sterile Powder, and Sterile Film*," (May 1997): pgs. 1 - 34.

Pharmacia & Upjohn Manufacturer Brochure "*Gelfoam Sterile Powder*," (February 1996).

Pharmacia & Upjohn Manufacturer Specification "*Gelfoam Sterile Sponge, Sterile Powder, and Sterile Film*," (November 1996): pgs. 1 - 23.

Pharmacia & Upjohn Manufacturer Brochure, "*Gelfoam Sterile Powder*," Mar. 1996.

Pharmacia & Upjohn Manufacturer Brochure for Gelfoam, Sep. 1996.

Fandrich, Christian, et al., "Small Gauge Gelfoam Plug Liver Biopsy in High Risk Patients: Safety and Diagnostic Value", *Australasian Radiology*, Vol. 40, pgs. 230-234 (1996)

Di Seni, Riccardo, et al., "Part 1. Embolotherapy: Agents, Equipment, and Techniques", *Vascular Embolotherapy*, Vol. 4, pgs. 29 & 33.

S.A. Riley, et al., "Percutaneous Transhepatic Liver Biopsy with Tract Embolization", *Radiology*, Vol. 198 (1996): pgs. 769-774.

The documents are being submitted within 3 months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later, therefore no fee or certification is required under 37 C.F.R. § 1.97(b).

Copies of the listed documents were previously submitted in prior application Serial No. 09/382,160, filed August 24, 1999, upon which Applicants rely for the benefits provided in 35 U.S.C. § 120. In accordance with 37 C.F.R. § 1.98(d), copies of the listed documents are not included.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 

Adam J. Cermak
Registration No. 40,391

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: November 15, 2001